



CANNON BUILDING  
861 SILVER LAKE BLVD., SUITE 203  
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE  
**BOARD OF PHARMACY**

TELEPHONE: (302) 744-4500  
FAX: (302) 739-2711  
WEBSITE: [DPR.DELAWARE.GOV](http://DPR.DELAWARE.GOV)  
EMAIL: [customerservice.dpr@state.de.us](mailto:customerservice.dpr@state.de.us)

## **APPLICATION FOR PHARMACY-MANUFACTURER PERMIT INSTRUCTION SHEET**

### **When to File Application**

This is the application for facilities that manufacture or package drugs, toilet preparations, dentifrices, or cosmetics in Delaware.

File this application for a Pharmacy-Manufacturer license when applying for an initial license OR re-applying when a previous Delaware license has lapsed and is no longer renewable. Since these licenses are not transferable, you must also file this application to report when a manufacturer already licensed in Delaware:

- Changes ownership (controlling interest), or
- Relocates.

A Pharmacy-Manufacturer permit terminates automatically when the controlling interest in the facility changes, the facility's legal existence ends, or the business ceases to operate (24 *Del. C.* §2540 (d)).

### **How to Apply**

Please read and follow instructions carefully. Failure to follow instructions may delay your application.

- ☐ Submit completed, signed and notarized [Application for Pharmacy-Manufacturer Permit](#).
  - Applications that are incomplete, unsigned or not notarized will be rejected.
- ☐ Enclose non-refundable [processing fee](#) by check or money order made payable to the "State of Delaware."
- ☐ If the firm is registered with the Food and Drug Administration or Drug Enforcement Administration, enclose results of last GMP inspection.
- ☐ Enclose *Manufacturer Permit–Information about Ownership* forms for **all** of the following:
  - Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control
  - Supervisor of the DR or most senior person responsible for facility operations, purchasing and inventory control
  - If the distributor is not a publicly held company, **all** principals and owners who directly or indirectly own more than 10% interest in the company
- ☐ Each person who is required to complete a *Manufacturer Permit–Information about Ownership* form must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.

### **Inspection Requirement**

In addition to meeting the requirements above, the facility must be inspected before opening. A representative of the manufacturer must notify the Board office when the facility is ready for inspection. When the facility passes the final inspection, the Board office will issue the license.

## Reporting a Manufacturer Name Change

If the facility's name changes, but **there is no change in ownership nor in location**, it is not necessary to submit an *Application for Pharmacy-Manufacturer Permit*. Instead, submit:

- ☐ Letter notifying the Board of the change that includes the manufacturer's old name and new name, license number and effective date of the change.
- ☐ [Duplicate license fee](#) by check or money order made payable to the "State of Delaware."
  - The duplicate license will show the new name, but the license number will not change.

## Controlled Substances Registration

If the facility also manufactures controlled substances, a separate [Controlled Substances Application for Facilities](#) application is required.

**A manufacturer must have a Delaware Pharmacy-Manufacturer permit, Delaware controlled substance registration and federal DEA permit before manufacturing controlled substances in Delaware.**



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**BOARD OF PHARMACY**

**For Board of Pharmacy  
Use Only**

- ☐ Verification  
☐ Background  
☐ Office Approval  
☐ Inspection

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**APPLICATION FOR PHARMACY-MANUFACTURER PERMIT**

**TYPE OF APPLICATION**

1. Select the items that describe the type of application:

- ☐ Initial Application –  
☐ This manufacturer has never held a Delaware Pharmacy-Manufacturer license.  
☐ This manufacturer previously held Pharmacy-Manufacturer license number **A5-** \_\_\_\_\_ that  
has lapsed and is no longer renewable.  
☐ Application Due to Change of Ownership – Pharmacy-Manufacturer license number **A5-** \_\_\_\_\_  
☐ Application Due to Relocation of Facility – Pharmacy-Manufacturer license number **A5-** \_\_\_\_\_

**CONTACT AND LOCATION INFORMATION**

2. Name of Business (as it should appear on license): \_\_\_\_\_

3. Enter all other trade or business names you use (or have used) such as “doing business as” or “formerly known as”  
names: \_\_\_\_\_

4. **Location (Site of Manufacture) Address:** \_\_\_\_\_  
Street (No PO Boxes)

\_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

5. Phone: \_\_\_\_\_ Email: \_\_\_\_\_

6. **Mailing Address** (if different from physical location): \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

7. Name of Contact Person: \_\_\_\_\_ ☐ Owner ☐ Manager ☐ Other

8. Phone (if different from physical location): \_\_\_\_\_ Email: \_\_\_\_\_

**INFORMATION ABOUT OWNERSHIP**

9. Form of Business (check one):  
☐ Corporation ☐ Partnership ☐ Sole Proprietorship  
☐ Individual with federal employee identification number

10. Enter the name of the Designated Representative (DR) or most senior person responsible for facility operations,  
purchasing, and inventory control: \_\_\_\_\_

**Enclose a *Manufacturer Permit–Information about Ownership* form for this person. This person must also  
complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal  
Bureau of Investigation criminal background checks.**

11. Enter the name of the supervisor of the person named above: \_\_\_\_\_ **Enclose a *Manufacturer Permit–Information about Ownership* form for this person. This person must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.**
12. Is this business a publicly held company? Yes ☐ No ☐ **If no, list the names of the principals and owners who directly or indirectly own more than 10% interest in the company.**

_____	_____
_____	_____
_____	_____
_____	_____

**Enclose a *Manufacturer Permit–Information about Ownership* form for each person listed. Each person listed must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.**

13. Do you understand that the Board must be notified within ten days of a change of ownership? Yes ☐ No ☐
14. Federal Employer Identification Number: \_\_\_\_\_

#### **LICENSURE HISTORY**

15. Does the manufacturer hold any state or federal licenses, registrations, or permits authorizing the manufacture of drugs? Yes ☐ No ☐ **If yes, attach a list of license/registration/permit numbers and the jurisdiction that issued them.**
16. Is the firm registered with the Food and Drug Administration or Drug Enforcement Administration? Yes ☐ No ☐ **If yes, enter the following information and enclose results of last GMP inspection.**
- Registration Number: \_\_\_\_\_ Date of Last GMP Inspection: \_\_\_\_\_

#### **SUPERVISION OF MANUFACTURING**

17. Enter the names of supervisor(s): \_\_\_\_\_  
If you need more room, attach a separate sheet.
18. Is each supervisor listed qualified by scientific or technical training, education or experience to perform the duties of supervision that are necessary to protect public health, safety and welfare? Yes ☐ No ☐

#### **PRODUCTS**

19. List the products the facility will package or manufacture: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

20. Will you manufacture controlled substances? Yes ☐ No ☐

<b>A manufacturer must have a Delaware Pharmacy-Manufacturer permit, Delaware controlled substance registration <u>and</u> federal DEA permit before manufacturing controlled substances in Delaware.</b>
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**When your application is complete, please allow 4-8 weeks to receive your license. A complete application is one that includes all required documentation and correct payment. Applications that are not complete within six months of filing may be considered abandoned and discarded.**

## AFFIDAVIT

I do hereby make application to the Board of Pharmacy for license or registration under the provisions of an Act to regulate the practice of Pharmacy in the State of Delaware and solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Printed Name: \_\_\_\_\_ Title: \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

State of \_\_\_\_\_ County of \_\_\_\_\_

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 2\_\_\_\_\_

Witness my hand and seal hereunto attached.

SEAL

Notary Signature: \_\_\_\_\_

My Commission expires: \_\_\_\_\_

***APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY  
THE REQUIRED PROCESSING FEE WILL BE REJECTED.***



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**MANUFACTURER PERMIT—INFORMATION ABOUT OWNERSHIP**

**INSTRUCTIONS**

Complete and submit one of these forms for each of the following persons listed on the *Application for Manufacturer Permit*:

- Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control
- Supervisor of the DR or most senior person responsible for facility operations, purchasing and inventory control
- If not a publicly held company, *all* principals and owners who directly or indirectly own more than 10% interest in the company

Each person completing one of these forms must also complete the *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.

1. Name of Manufacturer: \_\_\_\_\_
2. Name: \_\_\_\_\_  
Last Name First Name Middle
3. Type of Interest in Manufacturer Named Above (check one):  
☐ Sole Proprietor ☐ Partner ☐ Individual with federal employee identification number  
☐ Corporate Officer – Position: \_\_\_\_\_  
☐ Designated Representative ☐ Designated Representative's Supervisor
4. Social Security Number: \_\_\_\_\_ Date of Birth: \_\_\_\_\_
5. Mailing Address: \_\_\_\_\_  
City State Zip
6. Phone: \_\_\_\_\_ Email: \_\_\_\_\_
7. Has any state or federal agency taken any type of disciplinary action against you or is any such action pending?  
Yes ☐ No ☐ **If yes, enclose a list of all disciplinary actions by state and federal agencies against you.**
8. Have you ever been arrested, interviewed, interrogated, convicted, received a criminal summons, received a civil citation by any police/law enforcement agency, college/university or campus police or security agency? **Note:** This includes DUI's and all juvenile arrests and cases even if dismissed for any reason whatsoever. The *only* exceptions are minor traffic citations. Yes ☐ No ☐ **If yes, list each charge separately below and give details on a separate page.**

ARREST DATE	ORIGINAL CHARGE	LOCATION OF ARREST (city and state)	ARRESTING POLICE DEPARTMENT	DISPOSITION (e.g., guilty, not guilty, dismissed, etc.)

9. Has a criminal indictment, information, or complaint ever been returned against you, but for which you were not arrested or which you were named as an un-indicted co-party? Yes ☐ No ☐ **If yes, give details on a separate page.**
10. Have you ever received a pardon or expungement for any criminal offense? Yes ☐ No ☐ **If yes, give details on a separate page. Include the charge, date, city, county and state.**
11. Have you ever been, or are you now, on parole/probation to any court? Yes ☐ No ☐ **If yes, give details on a separate page. Include the charges, the name of your parole/probation officer, location including city, county and state where probation was/is served.**
12. Have you ever been civilly or criminally subpoenaed to appear to testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐ **If yes, give details on a separate page. Include the location and reason for being subpoenaed.**

**Complete the *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks. Follow instructions on the form for submitting fingerprints. The State Bureau of Identification will send the reports directly to the Board office.**

### **AFFIDAVIT**

I solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

State of \_\_\_\_\_ Country of \_\_\_\_\_

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 2\_\_\_\_\_

Witness my hand and seal hereunto attached.

SEAL

Notary Signature: \_\_\_\_\_

My Commission expires: \_\_\_\_\_

# Instructions for Requesting a Criminal Background Check

**Both State of Delaware and Federal Bureau of Investigation criminal background checks are required.**

## Applicant Notification

Your fingerprints will be used to check the criminal history records of the Federal Bureau of Investigation (FBI). You have the opportunity to challenge the accuracy of the information contained in the FBI identification record. See [Title 28, CFR 16.34](#) for the procedure to obtain a change, correction or update in the FBI record.

## Locations

### **Kent County – Primary Facility**

State Bureau of Identification  
Blue Hen Mall & Corporate Center  
655 S. Bay Rd. Suite 1B  
Dover, DE 19901

**Walk-ins accepted:** Mon 8:30 am – 6:30 pm, Tue - Fri 8:30 am – 3:30 pm  
Customer Service: (302) 739-2134

### **New Castle County - Satellite Facility**

State Police Troop Two  
100 LaGrange Ave  
Newark, DE 19702  
(between Rts. 72 and 896 on Rt. 40)  
**By appointment only**  
Scheduling: (302) 739-2528 (local)  
(800) 464-4357 (toll free)

### **Sussex County – Satellite Facility**

Thurman Adams State Service Center  
546 S. Bedford Street, Rm. 202  
Georgetown DE 19947  
(across from DelDOT & Troop 4)  
**By appointment only**  
Scheduling: (302) 739-2528 (local)  
(800) 464-4357 (toll free)

## Applicants in Delaware

1. If you are using the New Castle County or Sussex County locations, call **(800) 464-HELP (4357)** to schedule an appointment. No appointments are needed at the Kent County location.
2. Take the completed *Authorization for Release of Information* form to one of the offices listed above with the fee of \$65.00, to cover both the State of Delaware and Federal Bureau of Investigation criminal checks. Money orders and credit cards other than American Express are accepted at all locations. New Castle and Kent Counties accept cash; Sussex County does not accept cash. **Personal checks are not accepted in any county.** As fees are subject to change, contact the agency where you plan to submit your forms for current fees.

## Applicants Not in Delaware (including Out-of-State or Outside the United States)

1. Your local police agency can fingerprint you. All types of fingerprint cards are accepted. Or, you may print a [FD-258 fingerprint form](#) available on the FBI website at [www.fbi.gov](http://www.fbi.gov) – click *Services*, then *Identity History Summary Checks*, then scroll down to Option 1, Step 2, and click the link for *standard fingerprint form (FD-258)*. You may print the form on regular paper.
2. Your *Authorization for Release of Information* form and the fingerprint card must be complete. If identifying information is missing (such as name, date of birth, race, gender, etc.), your form will be returned.
3. **Mail** the *Authorization* form, fingerprint card, and *certified* check or money order (**personal checks are not accepted**) for \$65.00 made payable to “Delaware State Police” to:

**Delaware State Police  
State Bureau of Identification (SBI)  
PO Box 430  
Dover, DE 19903-0430**

**DO NOT SEND THIS FORM OR FEE TO YOUR PROFESSION'S BOARD OFFICE.**  
**DO NOT SEND THIS FORM OR FEE TO THE DIVISION OF PROFESSIONAL REGULATION.**  
**⇒ ALLOW FOUR WEEKS FOR RECEIPT OF RESULTS.**





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**AUTHORIZATION FOR RELEASE OF INFORMATION**  
**CRIMINAL HISTORY RECORD CHECK FOR PROFESSIONAL LICENSURE APPLICANTS**

*Please print or type all information in black ink.*

**Check the type of license for which you are applying:**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> Adult Entertainment   | <input type="checkbox"/> Mental Health (LPCMH, LCDP, LMFT, LAPCMH, LAMFT)                              | <input type="checkbox"/> Physical Therapy/Athletic Trainer                             |
| <input type="checkbox"/> Charitable Gaming Vendor  | <input type="checkbox"/> Nursing (RN, LPN, APRN)   | <input type="checkbox"/> Podiatry  |
| <input type="checkbox"/> Chiropractic  | <input type="checkbox"/> Nursing Home Administrator  | <input type="checkbox"/> Psychology  |
| <input type="checkbox"/> Dental  | <input type="checkbox"/> Occupational Therapy  | <input type="checkbox"/> Real Estate Appraiser (includes Appraisal Management Company) |
| <input type="checkbox"/> Funeral   | <input type="checkbox"/> Optometry   | <input type="checkbox"/> Speech/Hearing  |
| <input type="checkbox"/> Massage   | <input type="checkbox"/> Pharmacy (includes key personnel of facilities licensed by Board of Pharmacy) | <input type="checkbox"/> Social Work   |
| <input type="checkbox"/> Medical (Physicians, Physician Assistants, Respiratory Care Practitioners, Eastern Medicine Practitioners, Acupuncture Practitioners, Genetic Counselors, Polysomnographers, Midwifery Practitioners (CM, CPM)) |  | <input type="checkbox"/> Texas Hold'em Individual                                      |

**Print your current full name:**

\_\_\_\_\_  
Last Name First Name Middle Initial Suffix (e.g., Jr., Sr.)

**Enter all other names you have used in the past (including, but not limited to, maiden name, former married names, alternative spellings):**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

As an applicant, I authorize release of any and all information that you have concerning my **CRIMINAL HISTORY RECORD INFORMATION**. I hereby release you, your organization, the State of Delaware and others from any liability or damage which may result from furnishing this information:

**SIGNATURE OF PERSON PRINTED:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Phone: Home \_\_\_\_\_ Work \_\_\_\_\_

**Mail the results of my criminal history request to:**

**Division of Professional Regulation  
861 Silver Lake Boulevard, Suite 203  
Dover DE 19904  
SLC D420A**

**USE OF CRIMINAL HISTORY RECORD INFORMATION IS RESTRICTED BY LAW AND SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS GIVEN. MISUSE CONSTITUTES A CRIMINAL VIOLATION.**